



Scott McCallum
Governor

A Newsletter of the PHARMACY EXAMINING BOARD

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Pharmacist to Technician Ratio

Phar 7.015 was created and effective May 1, 2001 defining a pharmacy technician and the technical dispensing functions which may be delegated. The entire text of Phar 7.015 was published in the October 2001 Regulatory Digest. In addition, the ratio was increased effective on the same date. Phar 7.01 (3) states "A pharmacist may supervise no more than one pharmacy intern and 4 pharmacy technicians engaged in compounding and dispensing activities as described in sub. (1), except a higher ratio may be authorized by the board upon request to and approval by the board of a specific plan describing the manner in which additional interns or pharmacy technicians shall be supervised." The Board emphasizes that this ratio sets a maximum allowed. Each pharmacist should use their professional judgment in deciding how many technicians they can appropriately delegate to and supervise.

Dispensing Requirements for Controlled Substances

The PEB has revised Phar 8.05, the dispensing requirements for controlled substances, removing the 7-day date limitation on schedule II controlled substances prescriptions and eliminating the 34-day dispensing quantity limitation on all controlled substances. The repeal of these sections of Phar 8.05 is intended to allow practitioners and pharmacists to more fully exercise their professional judgment in prescribing and dispensing controlled substances. This is consistent with federal controlled substances prescription rules which have no date or days supply restrictions. The state requirement that a schedule II controlled substance prescription may not be dispensed more than 60 days after the date of issue still remains. Phar 8.05 (4) now reads "A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order." Phar 8.05 (5) is repeated in its entirety. These changes were effective August 1, 2002.

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Minimum Equipment

Chapter Phar 6.06 has been modified by the Pharmacy Examining Board (PEB) to clarify and update the standards for minimum equipment to be contained in the service area of a pharmacy. Key modifications include recognition that an electronic as well as a torsion balance is permitted, deletion of reference to the national bureau of standards handbook 44, and recognition that statutes and rules may be made available via electronic means and therefore now allows for immediate accessibility to those statutes and rules as satisfying that portion of the rule (via Internet access).

These changes became effective **September 1, 2001**.

The full text of Phar 6.06 may be found at www.drl.state.wi.us.

Proof of Ability to Practice as a Pharmacy Intern While Enrolled as a Student or While Waiting for Licensure

The new rules that govern pharmacy internships in Wisconsin do not include the issuing of an intern license as was the procedure by the Pharmacy Internship Board. Many employers of pharmacy interns have in the past asked for a copy of the intern license as proof that the person could legally practice as an intern in Wisconsin. For academic or student non-academic internships (these are the two categories that apply before graduation), the employer may ask the student to supply proof from their school of pharmacy, such as transcripts or a letter from the Dean, that they have "successfully completed his or her second year in, and is enrolled at, an accredited school of pharmacy" as required by Wisconsin Statute 450.03 (f) and Phar 17.07.

Under Wisconsin Statute 450.03 (g) "a person who has applied for a license" may practice under the direct supervision of another pharmacist "during the period before which the board takes final action on the person's application". Two methods that postgraduate interns, foreign graduate interns, and out-of-state pharmacists waiting for licensure can produce proof for their employers are 1) show the employer the pending status of their application on the Department of Regulation and Licensing (DRL) web site or 2) request a letter of verification from the DRL that there is a pending application on file. There is a \$10 fee for a letter of verification.

Review of Requirements for Wisconsin Licensure of a Pharmacist Licensed in Other States

Chapter 450.05 is the Wisconsin statute which delineates the requirements for pharmacists licensed in other states to reciprocate their license to Wisconsin. First, the pharmacist may not be licensed in Wisconsin under this section if their license has been surrendered, limited, suspended or revoked in another state. Such an applicant would need to meet original licensure requirements. Secondly, the pharmacist must be engaged in the active practice of pharmacy as defined in Phar 2.06(2). That definition states "active practice of pharmacy" means having engaged in at least 2,000 hours of the practice of pharmacy within the 12 months preceding application for licensure in Wisconsin or at least 2,000 hours of the practice of pharmacy comprised of no less than 500 hours in each of 3 of the 4, 12-month periods preceding application for licensure in Wisconsin. If the out-of-state licensed pharmacist meets the above two requirements, the reciprocal candidate upon submitting a completed application and applicable fees, is only required to take the Wisconsin version of the multi-state pharmacy jurisprudence exam (MPJE). Phar 2.06 has been amended to reflect this requirement.

Schedule V Controlled Substance Register

A pharmacist asked the PEB for an opinion on whether the privacy rules of the Health Insurance Portability and Accountability Act (HIPAA) regulations will affect the use of the bound Schedule V controlled substance register that is required in Wisconsin. Since the controlled substance, i.e. cough syrup is being sold as an over-the-counter (OTC) medication, the Board views this type of sale as not be subject to the same privacy standards as HIPAA regulations will have on prescription records.

Your Signature and What it Means

Licensees are responsible for the signing of any form, application, affidavit, or checklist attesting to the completeness and accuracy of all the information provided to the Board. Providing false information is a violation of Phar 10.03(8) and will be forwarded to the Division of Enforcement for investigation. Phar 10.03 states "Unprofessional conduct. The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under 450.10(1), Stats.:..... (8) Providing false information to the pharmacy examining board or its agent."

Business Models and the Requirements for Licensure

The following informational article was written by the Board's legal counsel, William Black, and is provided to business entities to be used as an aid in determining whether or not they need a particular license to do business in Wisconsin.

Drug manufacturers

1. Drug or device manufacturing facilities which are located within the state of Wisconsin are required to obtain a manufacturer's license from the board. If the Wisconsin facility also directly distributes these pharmaceuticals at wholesale a distributor's license is also required.
2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.
3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.
4. A distributor's license would be required for an out-of-state manufacturing facility if it engages in the wholesale distribution of prescription drugs or devices in this state from that manufacturing facility.
5. Any other distribution facility located in-state or out-of-state, whether or not owned by the manufacturer, must be licensed as a distributor if it engages in the wholesale distribution of prescription drugs or devices in this state.
6. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity. This means that a manufacturer can ship prescription drugs and devices from its manufacturing facility (in-state or out-of-state) to a distributor facility (in-state or out-of-state) which are both under common ownership or control without the need for

the manufacturing facility to also be licensed as a distributor.

Prescription drug distributors

1. A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. [See, sec. 450.07 (3), Wis. Stats.]. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.
2. Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.
3. Distribution by company A of prescription drugs under the label of company B. A distributor's license is required in this state for the facility that distributes a prescription drug into (or in) Wisconsin, irrespective of where that facility is located. The fact that the distributor (company A) may also manufacture the product under a different label does not require a separate manufacturer's license unless the facility is physically located in this state. Nor does Wisconsin law require that the entity whose label is being utilized (here, company B) be licensed as a distributor or manufacturer in this state.
4. Company A recently acquired ownership of certain prescription and OTC products previously distributed by company B along with the right to the use company B's name. The products, themselves, will continue to be distributed from facilities which are currently licensed as wholesale distributors in this state. Company A does not own or operate any of the licensed distributor facilities. Company A is not required to obtain a wholesale distributor's license from this state. A distributor's license is required in Wisconsin for each facility which distributes prescription drugs at wholesale. Although the ownership of the prescription medications being distributed at wholesale has changed, the owner of the licensed distributor facilities has not. Mere "ownership" of prescription drugs or devices

being distributed does not require a distributor's license.

5. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity.

Out of state Pharmacies

1. This state does not require a Wisconsin pharmacy license be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state. Wisconsin does not license out-of-state pharmacies at this time.

Repackaging Guidelines

The following guidelines concerning the issue of repackaging previously dispensed drugs have been prepared by William Black, legal counsel, and approved by the Wisconsin Pharmacy Examining Board.

Where a previously dispensed drug (by a practitioner or a pharmacy) is later taken to a pharmacy by a patient to be repackaged, the issue arises as to the proper label to be affixed to the repackaged prescription and whether repackaging is even proper.

A. Applicable state law - Wis. Admin. Code § Phar 7.04 (4)

Phar 7.04 (4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.

Repackaging requests consist of several scenarios as follows:

1. Previously dispensed drug sample by a prescriber, not containing a label.
2. Previously dispensed drug non-sample by a prescriber, appropriately labeled as per Wis. Stat. § 450.11 (4).

3. Previously dispensed drug non-sample by a pharmacy, appropriately labeled as per Wis. Stat. § 450.11 (4), to be repackaged by the non-dispensing pharmacy.
4. Previously dispensed drug non-sample by a pharmacy, appropriately labeled as per Wis. Stat. § 450.11 (4), which was previously dispensed by that pharmacy.

By repackaging a previously dispensed drug, the pharmacist is acting as the agent of the patient. Therefore as a threshold issue with any repackaging the pharmacist must assure him/herself that the drug to be repackaged is not defective, adulterated, misbranded, or repackaged for use beyond its expiration date. The professional duty requirements for patient safety codified at Wis. Admn. Code chapter Phar 10 should be reviewed for compliance.

These issues are of paramount importance because legal liability may attach to a pharmacy that allows pharmacists to repackage previously dispensed drugs. The pharmacist and pharmacy should insure that legal/risk management issues and regulatory liability issues are explored with independent legal counsel and addressed by appropriate policies and procedures.

B. Federal Repackaging Requirements

Federal law pertaining to drug manufacturing, distribution, dispensing and approval of drugs is set within the parameters of the federal Food, Drug & Cosmetic Act as amended, 21 U.S.C. § 301, (the "Act").

The Act's intent can be summarized generally to prohibit the adulteration (21 U.S.C. § 351) or misbranding (21 U.S.C. § 352) of drugs in interstate commerce and to provide a mechanism to approve new drugs (21 U.S.C. § 355). To achieve these goals manufacturers, distributors and practitioner/dispensers are regulated in concert with applicable state law. The federal Food and Drug Administration (FDA), in part, administers rules to implement the act and issues policy guidelines setting forth its interpretation of the Act and rules.

Within interlocking federal and state statutes, rules and policy guidelines, the basic focus of the Act as outlined above can at times be lost. The problem of repackaging a previously dispensed prescription drug presents an example where focus on the intent of the Act must be maintained. At the point in time that a non-adulterated, non-misbranded approved drug has been properly

dispensed and labeled pursuant to a properly prepared prescription drug order, the goals of the Act have been achieved.

Post dispensing, it is the patient's choice to store, use or dispose of drugs in any manner not otherwise illegal (i.e. diversion, prohibited returns, prohibited transfers). The patient may therefore employ agents to assist in what may be termed, "drug therapy management". Family, friends, coworkers, employed agents, volunteers; all may act at the direction of the patient. The misconception has arisen that a pharmacist may not perform a professional role to assist a patient in drug therapy management through repackaging previously dispensed prescription drugs.

The pharmacist is the specific agent whom reason would dictate should be involved in post dispensing repackaging. To prohibit a pharmacist from repackaging a previously dispensed drug would create the anomaly whereby a friend or family member or the patient him/herself could repackage a drug yet a trained professional could not.

C. Confusion over the term "repackaging"

It appears that where confusion regarding the term "repackaging" exists, it arises from the confusion over two separate terms of art deemed "repackaging".

In the post dispensing context, the term "repackaging" is used to denote the removal of a dispensed drug from the container in which it was dispensed (or other packaging into which the drug was subsequently transferred by the patient) and to place it into another container. No "original", "bulk" or "manufacturer's" container is involved in this process.

By contrast, 21 CFR § 201.150 also uses the term "repacking" in providing an exemption from certain labeling and packaging requirements of the Act. However, the section 201.150 exemption relates to *pre-dispensing* activities of manufacturers or for any class of persons who engage in "repacking".

Where the Act and rules refer to an exemption from labeling requirements that apply generally to a manufacturer or distributor, it is in the context of *dispensing*. 21 CFR § 201.100(a)(2). However, the Act and rules are silent regarding post dispensing labeling requirements. The 21 CFR § 201.100(a)(2) exemption is but one example that the focus of the Act and rules are related to pre-dispensing restrictions to insure that

non-adulterated, non-misbranded and safe and effective drugs are ultimately *dispensed* in the appropriate manner. (See also, *Prohibited Acts*, 21 U.S.C. § 331; and *FDA CPGs* 7132b.10, 7132b.11 and 7132.13, *infra*, which also apply to "repacking" in the pre-dispensing context.)

A repackager of *non-dispensed* drugs for purposes of dispensing or administration must comply with the following federal Food and Drug Administration (FDA) policy guidelines. The FDA policy guidelines provide internal cites to the Act and indicated CFR section(s) and interpret how those sections apply to repackaging within the distribution chain.

- 1) Repacking of Drug Products - Testing/Examination under CGMPs (CPG 7132.13)
- 2) Unit Dose Labeling for Solid and Liquid Oral Dosage Forms (CPG 7132b.10)
- 3) Expiration Dating of Solid and Liquid Oral Dosage Forms in Unit Dose Containers. (CPG 7132b.11).

Note, however, that the referenced CPGs apply to repackers of drugs in the chain of distribution prior to dispensing or for the purpose of dispensing. A repacker of unit dose medications could certainly be a pharmacist in this context, (i.e. for inpatient drug delivery systems), and the guidelines and comments specifically contemplate this scenario. However, this type of repackaging is pre-dispensing/administration by its very terms. The referenced CPGs illustrate that the repackaging addressed is of the pre-dispensing type.

D. Repackaging of previously dispensed prescription drugs.

Board policy approves repackaging of previously dispensed drugs with their subsequent return to the patient. The pharmacist should exercise professional judgment to determine whether it will be safe to serve the patient in this manner. With any repackaging request the pharmacist must assure him/herself that the drug to be repackaged is not defective, adulterated or misbranded and that directions for use can reasonably be ascertained.

A pharmacist should consider the following factors when engaging in repackaging for a patient under Wis. Admin. Code § Phar 7.04 (4). The pharmacist should use professional judgment to determine which of the factors apply, depending upon individual circumstances.

1. Use of the original label where possible.

The use of the word "relabeling" in section Phar 7.04 (4) is intended to apply to circumstances where the original container of a previously dispensed drug was labeled, and that specific dispensing label is to be thereafter transferred by the pharmacist to new packaging for the patient. However, in the instance of a dispensed sample drug pursuant to Wis. Admin. Code § Med 17.04 (2), typically no original dispensing label will be available.

The original dispensing label should be retained and reapplied where possible with additional informational labels as necessary.

2. Use of an informational "repackaging label"

The underlying patient safety and professional accountability rationale of the labeling requirements for original dispensing contained in Wis. Stat. § 450.11 (4), apply to repackaging and relabeling by implication through Wis. Admin. Code Chapter Phar 10.

The duties of a repackaging pharmacist to insure patient safety and document professional accountability are in some respects even greater than in the instance of original dispensing. The reason is that the drugs have for a period of time been out of the possession of a licensed professional and contamination/storage/adulteration and diversion possibilities become a concern. Moreover, in the case of samples, there may be no original directions for use contained on the container, and the identity of or access to the original prescriber to verify directions for use may be difficult or impossible to achieve.

For a repackaging informational label, the requirements of Wis. Stat. § 450.11 (4) (a) should be adhered to where possible, with appropriate modification as necessary to indicate the "repackaging" practitioner as opposed to the "dispensing practitioner."

3. Assuming that patient safety and pharmacy policy allows repackaging the following additional considerations apply to a pharmacist when requested to repackage a previously dispensed drug.

a. Contact the practitioner who prescribed the drug when necessary and/or review any prescriber medication order.

b. Document the repackaging process and keep a record of what steps were taken to obtain information and relabel the repackaged drug. Often, some type of "prescription order" number of the type contemplated by Wis. Stats. § 450.11(4)(a)(3), will be warranted to code the repackaging in the pharmacist's recordkeeping system to provide proper accountability and tracking of who performed what function. Risk management analysis between the pharmacy/pharmacist and liability insurer may dictate additional record keeping requirements.

c. Conform to any special labeling requirements administered by another agency of this state. In particular, review applicable HFS rules.

d. Consideration should be given whether and when to separate repackaged drugs from other drugs that will be contemporaneously packaged for original dispensing for a particular patient. Depending upon the drug to be repackaged and the factual context regarding the patient's or a facility's need, separation may be advisable. Separation of repackaged drugs will often be necessary if commingling would interfere with later accounting and identification of the original dispensed drugs in the event of a possible return. Commingling may therefore not be possible where the repackaged drugs cannot later be identified to prevent inadvertent redispensing to another patient in the instance where the commingled drugs are returned.

e. The pharmacist may always return the drug to the prescribing practitioner, nurse or other practitioner for repackaging.

f. The pharmacist always retains the option to refuse to repackage.

In any given repackaging circumstance the pharmacist is being called upon to use professional judgment on behalf of a patient to assist in managing that patient's drug therapy. The pharmacist is directed to consult independent legal counsel and review any applicable risk management/insurance issues that may apply to constrain the pharmacist's ability to repackage previously dispensed drugs on behalf of a patient.

DISCIPLINARY ACTIONS

The disciplinary summaries are taken from orders that can be reviewed on the Department of Regulation and Licensing Web site: www.drl.state.wi.us. Click on "Publications" and then "Reports of Decisions" to view the order. Decisions reported below may have an appeal pending and the discipline may be stayed. The current status of the discipline may be viewed on the Department's Web Site under "License Lookup," by calling (608) 266-2112, or by checking the progress of cases in court at: www.courts.state.wi.us.

DAVID M SMITH RPH

ELM GROVE, WI REPRIMAND/COSTS

Failed to properly make a final check on the accuracy and correctness of the filling of a prescription order. Dated 7-9-2002. Wis. Stat. 450.10(1)(a)(6), Wis. Admin. Code Phar 7.01(1)(d), (e), 10.03(2), (3). Case #LS0207092PHM

SOLUTIONS PHARMACY

MADISON, WI

REPRIMAND/COSTS/FORFEITURE

Failed to have a centrally monitored alarm system. Costs of \$100.00 and a forfeiture of \$1,000.00. Dated 7-9-2002. Wis. Admin. Code Phar 6.08. Case #LS0207093PHM

SCENIC BLUFFS COMM HEALTH CNTR

CASHTON, WI

REPRIMAND/FORFEITURES/COSTS

In August, 2001, the pharmacy alarm system was deficient in that it was not continually monitored 24 hours a day. Costs of \$400.00 and a forfeiture of \$1625.00. Dated 5-14-2002. Phar 6.08, Wis. Admin. Code. Case #LS0205141PHM

EVELYN M FULLER RPH

FRANKLIN, WI REPRIMAND/COSTS

As managing pharmacist did not recalculate a prescription or check the label for accuracy before dispensing the prescription to the patient. Costs of \$300.00. Dated 5-14-2002. Sec. 450.10(1)(a)6, Wis. Stats. Phar 7.01(1)(d),(e), 10.03(2), Wis. Admin. Code. Case #LS0205143PHM

HAYWOOD C ANDERSON RPH

MARINETTE, WI REPRIMAND/COSTS

A pharmacy technician entered an order that was barely legible and issued the prescription. No consultation occurred. The patient used the

drug for several days before the error was discovered. Costs of \$400.00. Dated 6-12-2002. Sec. Phar 10.03(3), Wis. Admin. Code Case #LS0206123PHM

JEFFRY J LANGFORD RPH

WASHBURN, WI

EDUCATION/REPRIMAND/COSTS

A medication error review revealed errors discovered in prescriptions filled by pharmacy technicians and verified by himself. Pay costs of \$400.00. Dated 6-12-2002. Sec. 450.10(1)(a)6., Wis. Stats. Phar 7.01(1)(d), 10.03(2), Wis. Admin. Code. Case #LS0206121PHM

JON D HERDRICH RPH

WEST BEND, WI

REPRIMAND/COSTS/FORFEITURES

As managing pharmacist failed to ensure that consultations were provided on refill prescriptions. Costs of \$250.00 and a forfeiture of \$250.00. Dated 5-14-2002. Phar 7.01(1)(e), Wis. Admin. Code. Case #LS0205144PHM

JAMES H TETEA RPH

HARTFORD, WI

REPRIMAND/COSTS/FORFEITURES

In February, 2002, failed to provide consultations on refill prescriptions. Costs of \$250.00 and a forfeiture of \$250.00. Effective 5-14-2002. Phar 7.01(1)(e), Wis. Admin. Code. Case #LS0205142PHM

LANCE J LUNDSTAD RPH

LA CROSSE, WI SUSPENDED/COSTS

Diverted bottles of hydrocodone liquid from patient and pharmacy supplies. Diverted benzodiazepines and prescription medications from the pharmacy. Charged in circuit court with a felony. Costs of \$400.00. Suspended for a period of not less than 5 years. Dated 6-12-2002. Sec. 450.10(1)(a)3., Wis. Stats. Phar 10.03(1), Wis. Admin. Code. Case #LS0206122PHM

JACK R ANDERSON RPH

MERRILL, WI

VOLUNTARY SURRENDER/COSTS

Took hydrocodone tablets from the pharmacy where he was employed, used some of the medication himself and delivered some to another person for cash. Dated 7-9-2002. Wis. Stat. 450.10(1)(a)(2), Wis. Admin. Code Phar 10.03(1), (2). Case #LS0207091PHM

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To discuss application questions:	press 1 - 3
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To renew or reinstate a permanent license:	press 1 - 4
To renew or reinstate a permanent license:	press 2 - 1
To renew a temporary license:	press 2 - 2
To obtain proof of licensure to another state:	press 3 - 1
To find out if a person is licensed:	press 3 - 2
To file a complaint on a license holder:	press 8
To check the status of complaints:	press 8
For all other licensing questions:	press 1 - 3

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Verifications are now available online at www.drl.state.wi.us. On the Department Web site, please click on "License Lookup". If you do not use the online system, all requests for verification of licenses/credentials must be submitted in writing. There is no charge for this service. Requests should be sent to the Department address or may be faxed to (608) 261-7083 - ATTENTION: VERIFICATIONS. Requests for endorsements to other states must be made in writing – please include \$10 payable to the Department.

DID YOU KNOW THAT YOU CAN ACCESS MOST INFORMATION ON THE DEPARTMENT OF REGULATION & LICENSING WEB SITE?

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CHANGE OF NAME OR ADDRESS?

Please photocopy the mailing label of this digest, make changes in name or address, and return it to the Department. Confirmation of changes is not automatically provided. **WIS. STATS. S. 440.11 ALLOWS FOR A \$50 PENALTY TO BE IMPOSED WHEN CHANGES ARE NOT REPORTED WITHIN 30 DAYS.**

WISCONSIN STATUTES AND CODE

Copies of the Wisconsin Statutes and Administrative Code relating to Auctioneers can be ordered through the Board Office. Include your name, address, county and a check payable to the Department of Regulation and Licensing in the amount of \$5.28. The latest edition of the Code Book is dated February 2002.